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International application number: PCT/US05/009650

International filing date: 23 March 2005 (23.03.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US
Number: 60/555,562
Filing date: 24 March 2004 (24.03.2004)

Date of receipt at the International Bureau: 25 April 2005 (25.04.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)

World Intellectual Property Organization (WIPO) - Geneva, Switzerland
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APPLICATION NUMBER: *60/555,562*
FILING DATE: *March 24, 2004*
RELATED PCT APPLICATION NUMBER: *PCT/US05/09650*

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)

Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Robert David	Kross	2506 Florin Ct. Bellmore, NY 11710

☐ Additional inventors are being named on the _______ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

Composition and Method for Dry Cow Udder Protection

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ENCLOSED APPLICATION PARTS (check all that apply)

☐ Specification Number of Pages [ ]
☐ Drawing(s) Number of Sheets [ ]
☐ Application Data Sheet. See 37 CFR 1.76
☐ CD(s), Number [ ]
☐ Other (specify) [ ]

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant claims small entity status. See 37 CFR 1.27.
☐ A check or money order is enclosed to cover the filing fees
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FILING FEE AMOUNT ($): 80

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Respectfully submitted,

SIGNATURE Robert D Kross

Date 3/19/04

TYPED or PRINTED NAME Robert D Kross

REGISTRATION NO. (if appropriate) [ ]

TELEPHONE 516 826-8747

Docket Number: [ ]

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This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($)

Complete if Known	
Application Number	
Filing Date	
First Named Inventor	Robert D Kross
Examiner Name	
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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	770	2001	385	Utility filing fee	
1002	340	2002	170	Design filing fee	
1003	530	2003	265	Plant filing fee	
1004	770	2004	385	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	80

SUBTOTAL (1) ($) 80

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

			Extra Claims		Fee from below		Fee Paid
Total Claims		-20** =		X		=	
Independent Claims		- 3** =		X		=	
Multiple Dependent						=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	86	2201	43	Independent claims in excess of 3
1203	290	2203	145	Multiple dependent claim, if not paid
1204	86	2204	43	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

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FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for *ex parte* reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	420	2252	210	Extension for reply within second month	
1253	950	2253	475	Extension for reply within third month	
1254	1,480	2254	740	Extension for reply within fourth month	
1255	2,010	2255	1,005	Extension for reply within fifth month	
1401	330	2401	165	Notice of Appeal	
1402	330	2402	165	Filing a brief in support of an appeal	
1403	290	2403	145	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive - unavoidable	
1453	1,330	2453	665	Petition to revive - unintentional	
1501	1,330	2501	665	Utility issue fee (or reissue)	
1502	480	2502	240	Design issue fee	
1503	640	2503	320	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Processing fee under 37 CFR 1.17(q)	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	770	2809	385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810	770	2810	385	For each additional invention to be examined (37 CFR 1.129(b))	
1801	770	2801	385	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	

Other fee (specify) ____________

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($)

SUBMITTED BY

(Complete *(if applicable)*)

Name *(Print/Type)*	Robert D. Kross	Registration No. *(Attorney/Agent)*		Telephone	516 826-8747
Signature	Robert D Kross			Date	March 19, 2004

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Composition and Method for Dry Cow Udder Protection

The dry period or non-lactating period of a cow is the approximate four to ten-week period immediately preceding the delivery of a calf. Although a typical cow's lactation period is about 300 days a year, it has been estimated that forty to fifty percent of teat infections occur during the cow's dry period. This high rate of infection occurs because the cow has a diminished immune response during the dry period, as well as the fact that the teat is distended during the dry period facilitating the penetration of the mammary gland by mastitis-causing organisms. And without the daily flushing by the milking process, infecting microorganisms are more likely to implant and proliferate. As a result, so-called dry-cow therapy has become an essential component of a mastitis control program.

Such therapy often involves the treatment of the udder with medication, which can beneficially remain within the udder tissue for extended periods, without it having to be discontinued several days prior to milking time so as to avoid their residues in the milk during the cow's lactation period. Such extended treatment would therefore minimize the rate of udder infections. And when and if the health of the cow can be restored during its dry period, it may then not have to be treated with antibiotics during its lactating period, which reduces the potential for residues of therapeutic agents during it lactation period.

During the active lactation period, mastitis is most easily controlled by using germicidal pre- and post-milking teat dip compositions. Such germicidal dips kill bacteria that are introduced onto the surface of the animal from many sources, including the milking machines, the milkers' hands, its bedding, and a host of environmental sources. The latter bacteria can impinge and remain on the cows' teats during the entire period between milkings, which can approximate 12-14 hours at times. The post-milking teat dips often include a film-forming agent, as well as the germicide. The film, or barrier, is intended to deposit an extra protective layer on the teat, and is designed to have sufficient retentive capacity to last through the inter-milking period, but also be readily removable when the cows' teats are cleaned prior to the subsequent milking. This represents an often difficult balancing act, between making the barrier film sufficiently resistant to environmental moisture, such as mud and rain, and having sufficient water solubility that it can be readily removed during the pre-milking water-rinse teat preparation. One such soluble barrier is the poly(acrylamido methanesulfonic acid) polymer, found in the currently marketed UdderGold series of teat dips. Another is the polyvinyl alcohol used in a number of teat dips. The former material enhances the viscosity of the teat dip; the latter does not. In general the films that they form, upon drying of the dip, can wear off in about 3 to 4 hours, depending upon environmental conditions. Dissolution and/or deterioration of the film is usually the greatest that when conditions are wet, and the barriers are, as a result, more-readily

removed. And under these conditions, the environmentally-associated bacteria are more likely to proliferate and have a greater potential for infection.

During the dry-period, however, it is possible to make use of a less water-soluble film material, so that the deposited film can remain in place for days or weeks, even under adverse climactic conditions. The film would, most importantly, form a plug at the teat end opening, and be a physical obstacle to the penetration of infectious bacteria. This film, as for the pre- and post-milking dips, would also be formulated to contain an antimicrobial material, or combinations thereof. The germicidal action of the antimicrobial(s) would not necessarily be as rapid, or as powerful as those that are used for the shorter-contact pre- and post-milking dips, since they would be in place for greater time periods. There are many antimicrobials that can fit into that category, including most of the single-phase systems in current use for lactating-associated dips, as well as others which may be slower-acting but appropriate for the dry-dip application.

U.S. Patent No. 6,440,442 by Erhard, *et al.* teaches a dry period teat dip comprising a dual polymer system; one component being a solvent-soluble, preformed, thermoplastic polyurethane and a second polymer component being a hydrophilic poly(N-vinyl lactam), said blend, upon evaporation of solvent, being capable of forming a water-resistant film upon topical application to mammalian skin without appreciable loss of the poly(lactam) through moisture in the environment. The composition also contains at least one antimicrobial agent, and it is reputedly capable of being removed by peeling. In earlier years, a latex-based dry dip was available, although antimicrobials were generally not compatible with these materials, and such barriers actually fomented the growth of bacteria between the barrier and the skin. Other recent coatings considered for teat dip application include polyvinylpyrrolidone and other vinyl polymers, protein hydrolyzate, and natural and synthetic gums.

Another product in current use is a paste, Orbeseal, which purportedly "provides a malleable barrier in the teat canal" and prevents bacteria from entering the teat canal during the dry period. It is infused, by syringe, into each quarter, and is subsequently removed by stripping before calving, or ingested by the calf, or eliminated during milking. It can, in the latter situation, cause blockage in the milking machine. This is cumbersome to apply, and eliminate, and currently costs about $2 to treat each cow. Other dry cow therapies that are standard in the industry include teat dip compositions that contain strong solvents, some of which (*e.g.,* tetrahydrofuran) are cytotoxic and cause irritation to skin, eyes and the respiratory tract. The irritation to skin includes symptoms such as redness, itching, rash, cracking and pain. Tetrahydrofuran is harmful if swallowed or inhaled, is an extremely flammable liquid, and repeated doses may cause kidney or liver damage, and may affect the lungs and central nervous system. peroxides.

The product taught by U.S. Patent No. 6,440,442 is a complex mixture of materials, relying on the physical entrapment of a soluble protective polymer within the structure of another polymer. The film is regarded as "water-resistant" rather than water-insoluble, so that it can slowly dissolve in the presence of excessive environmental moisture, and provide reduced protection. As a result of its complexity, the price for the commercial product, T-Hexx, is currently over $70 per quart. The present invention is the result of a search for a dry dip composition that forms an insoluble film on the teat, following application of a solubilized precursor polymer composition, which composition is economically more reasonable that current dry dips.

In the course of this search I have found that certain polar acrylate solutions have the ability to form insoluble films upon drying of their aqueous solutions. In particular I have identified certain preferred bimodal interpenetrating polymer networks which comprise both cationic and anionic functionalities which form stable aqueous solutions. These systems, however, during the drying process, rapidly interact with each other by forming ionic bonds between the polar chains, and become ionically crosslinked. These polymer systems are produced by a polymerization process in the presence of each other. Particularly preferred is the system categorized by the INCI name as "Styrene/Acrylates/Ammonium Methacrylate Copolymer (and) Butylene Glycol" and comprised of two acrylate copolymers with respective CAS Nos. Of 68541-61-7 and 16316-50-7, 1,3-butanediol and sodium laurylpolyethoxyethanol sulfate. Such systems, upon drying, whether on mammalian tissue or inanimate substrates, form water-insoluble films that adhere to the surface upon which they have dried. In general, the solids contents of these particularly preferred aqueous polymer solutions ranges from about 20% to about 30% by weight. The films of this invention are inherently water insoluble under environmental conditions characteristic of those which confront mammalian species, particularly cows and goats. They can remain on the animal for many days, particularly in the teat opening in which the solution would flow, accumulate and evaporate in larger quantities than on the sides of the teat. The films would remain substantially intact, despite exposure of the animal to environmental moisture such as rain, dew, ponds, and mud. Additionally, these films are moisture-vapor permeable, and permit transpiration of gasses and other volatile physiological compounds which are necessary for proper functioning of mammalian skin. And, if necessary, the compositions may be physically removed and, over time, if the film has been removed, they can be reapplied to restore the protective coating.

The viscosity of these systems may be partially controlled by upward pH adjustment, so as to increase the relative amount of acrylate anion *vs.* acrylic acid functionality. Those skilled in the art of polymer compounding and cosmetic formulation would be familiar with appropriate agents to effect such pH modification, where such agents would include ammonium salts and compounds of the ethanolamine family, as well as alkali and alkaline earth hydroxide compounds, such as sodium

and calcium hydroxide. The compositions may be suitably thickened, as well, by the use of appropriate thickening agents that are known to persons skilled in the art of compounding. Such thickening agents would include members of cellulosic family, such as sodium carboxymethyl cellulose, members of the Carbopol family, such as Carbopol 960, inorganic thickeners, such as the members of the hydrated silica family, and a range of natural and synthetic thickening agents, such as the xanthan gums, polyacrylamides, and members of the latter family, such as the sodium salt of polyacrylamido methanesulfonic acid.

A number of dermatologically-compatible solvents may be incorporated into these acrylate solutions, at appropriate degrees, so as to enhance the rapidity of evaporation of the film on the teat skin. These solvents should be non-cytotoxic and nonirritating to mammalian skin. Examples of such solvents include ethanol, isopropanol, ethyl lactate, diacetone alcohol, N-methyl pyrrolidone and mono and di-ethylene glycol ethers. Ethanol and isopropanol are the preferred solvents. Examples of antimicrobial agents used in the present composition include iodine, chlorhexidine, sodium dodecylbenzene sulfonate, nitrous acid, bronopol and triclosan.

In a preferred embodiment, the composition demonstrates thixotropic viscosity characteristics, and ranges in viscosity from about 500 to about 5000 cps, when measured with a Brookfield Viscometer at 20 rpm with a #3 spindle. This range in viscosity allows an adequate amount of the composition to deposit and remain on the mammalian teat, with low drip loss. After the mammalian teats have been coated with the composition of this invention, the resulting coating is permitted to dry to an adherent solid film on the teats. Typically, some of the still liquid coating material flows down to the teat end where a plug-like deposit is formed, to effectively seal off the teat canal.

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Robert D. Kross Date